DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 10, 2014

Stryker Trauma AG
Ms. Nesli Karakaya
Associate Regulatory Affairs Manager
Bohnackerweg 1
CH-2545 Selzach
Switzerland

Re: K140961
Trade/Device Name: Hoffmann LRF (Limb Reconstruction Frame) System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: September 29, 2014
Received: October 8, 2014

Dear Ms. Karakaya:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140961

Device Name
Hoffmann LRF (Limb Reconstruction Frame) System

Indications for Use *(Describe)*
The Stryker Hoffmann LRF (Limb Reconstruction Frame) System is indicated in pediatric patients and adults for the treatment and fixation of:

- Open and Closed Fractures
- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis or non-union of long bones
- Limb lengthening by epiphyseal or metaphyseal distraction
- Correction of bony or soft tissue deformity
- Correction of segmental bony or soft tissue defects
- Joint arthrodesis
- Management of comminuted intra-articular fractures of the distal radius

The Stryker Hoffmann LRF System is indicated in adults for:
- Osteotomy
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot foot reconstruction
- Lisfranc dislocations

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Proprietary Name:	Hoffmann LRF (Limb Reconstruction Frame) System
Common Name:	External Fixation Device
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3030
Regulatory Class:	Class II
Product Codes:	KTT-Appliance, fixation, nail/blade/plate combination, multiple components
Sponsor:	Stryker Trauma AG Bohnackerweg 1 CH-2545 Selzach Switzerland
Contact Information:	Nesli Karakaya, RAC Associate Regulatory Affairs Manager Bohnackerweg 1 CH-2545 Selzach Switzerland Phone: +41 32 641 69 30 Fax: +41 32 641 66 60 nesli.karakaya@stryker.com
Date Prepared:	April 10, 2014

Description:

Originally cleared in K113327, the Hoffmann LRF System is an external fixation device that consists of carbon and aluminum full/open rings and ring segments, aluminum foot rings, threaded rods and threaded rod connecting nuts, telescopic struts, static struts and connection bolts, posts and connecting nuts, wires and wire bolts, wire bolt offset adapters, pin bolts and pin adapters, and washers.

- Modifications to the previously cleared telescopic strut and wire bolt components, as part of the currently marketed Hoffmann LRF (Limb Reconstruction Frame) System in K113327, were cleared in K130334.
- Additional components (carbon foot ring, foot arch, hinge coupling) were cleared in K130907 as a line extension to the currently marketed Hoffmann LRF (Limb Reconstruction Frame) System in K113327.
- This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the inclusion of additional components to the previously cleared Hoffmann LRF (Limb Reconstruction Frame) System, in K130907. The additional components of this submission will consist of the following: constrained hinge strut,

universal hinge strut, motor struts, spherical washer, hinge bolt, self-locking nut, half hinge, universal joint, adjustment instrument, slotted plate and buckle.

This external fixation system may also be used with the components of other Stryker Trauma AG external fixation systems such as the Monticelli Spinelli External Fixation System, the Hoffmann II, Hoffman II MRI and Hoffmann 3 External Fixation System, and the Apex Fixation Pins.

Intended Use:
The Hoffmann LRF (Limb Reconstruction Frame) System is intended for fixation of fractures, joint contractures, fusions, limb lengthening, deformity correction, bone and soft tissue reconstruction in pediatric patients and adults.

Indications:
The Stryker Hoffmann LRF (Limb Reconstruction Frame) System is indicated in pediatric patients and adults for the treatment and fixation of:

- Open and Closed Fractures
- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis or non-union of long bones
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The Stryker Hoffmann LRF System is indicated in adults for:

- Osteotomy
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- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot foot reconstruction
- Lisfranc dislocations

Summary of Technologies:
Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the following predicate devices:

- Hoffmann LRF (Limb Reconstruction Frame) System- K113327/ K130334/ K130907
- External Fixation System (Smith and Nephew)- K031181

Non-Clinical Testing:
Non-clinical laboratory testing was performed for the Hoffmann LRF (Limb Reconstruction Frame) System on the additional components and component compatibility. Testing was

performed with compliance to ASTM F1541-02 – "Standard Specification and Test Methods for External Skeletal Fixation Device." Testing demonstrated that the Hoffmann LRF (Limb Reconstruction Frame) System added components are substantially equivalent to the predicate device components. Testing included the following:

- Static Cantilever Bending Test
- Dynamic Cantilever Bending Test
- Dynamic Frame Testing

  Static and dynamic compression tests

Clinical Testing: Clinical testing was not required for this submission.

Conclusion: The Hoffmann LRF (Limb Reconstruction Frame) System is substantially equivalent to the predicate devices identified in this premarket notification.